REMARKS/ARGUMENTS

Reconsideration is respectfully requested.

This communication responds to the Final Office Action of January 5, 2010, in which claims 1-37 are pending, and claims 1-20, 33, and 34 are withdrawn.

With this Response, no claims have been added or cancelled. Claims 21, 36, and 37 are amended. Thus, claims 1-20 and 6-58 remain pending

No new matter has been added. Support for amendments to claims 21, 36, and 37 may be found throughout the specification and claims as filed, for example at Figs. 2-5, and paragraph [0058]. .

Applicants have not publicly dedicated, or abandoned, any unclaimed subject matter. Further, Applicants do not acquiesce to any rejections made by the Examiner in the Office action, but have merely amended claims in an effort to expedite prosecution. Applicants reserve the right to pursue prosecution of any presently or previously excluded or cancelled claim embodiments in one or more future continuation and/or divisional applications.

I. Claim Rejections Under 35 U.S.C. §112

Claim 21 was rejected under 35 U.S.C. § 112 for failing to particularly point out and distinctly claim the claimed subject matter. The Examiner argues that the use of "implant adjustment instrument" in claim 21 lacks an antecedent basis.

Claim 21 is currently amended to recite "the implant insertion instrument," thus making explicit that which was previously implicit. Thus, this amendment does not change the scope of the claimed invention.

Claim 37 was rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Examiner argues that the claimed device "has not been described as 'monolithic' in the specification or the drawings."

Claim 37 is currently amended to recite "cortical bone formed from a transverse section slice taken from the diaphysis of a long bone," as described and shown throughout the specification, for example in paragraph [0058] and Figs. 3 and 3a.

II. Claim Rejections Under 35 U.S.C. §102

Claims 21, 22, 24, 26-29, 32, and 36 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Publication No. 2004/0078078 to Shepard ("Shepard"). Applicants disagree.

According to the M.P.E.P., "[a] claim is anticipated only if each and every" aspect of the claim "is found, either expressly or inherently described," within a single cited reference. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987)).

A. Shepard does not teach "the substantial entirety of said superior and inferior surfaces for load bearing against respective adjacent vertebrae," recited in present claims 21 and 36.

Shepard is directed to a "composite bone graft for use in implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." *Shepard,* Abstract. It is the "T-shaped cortical bone" that bears the load of the adjacent vertebrae, not the cancellous bone, which is described as having "lower mechanical strength . . . [which] prohibits its use in many surgical applications." Shepard is explicit, that the cortical bone, not cancellous bone, is load bearing and Shepard further describes the implant as "a two piece, mated bone fusion block or spacer constructed with one component member of load bearing material preferably cortical bone and the other component member made of cancerous [sic] bone for use in orthopedic surgical procedures." *Shepard,* para. [0021] (emphasis added). Moreover, Shepard notes that the cancellous bone is "the more brittle . . . portion of the graft," that must be protected from even tapping by a surgical instrument. *Id.,* [0063]. This is simply not the presently claimed implant wherein the "substantial entirety of said superior and inferior surfaces [are] for load bearing against respective adjacent vertebrae."

B. Shepard does not teach a "body having an outer peripheral surface substantially entirely of load bearing material," of present claims 21 and 36.

Again, Shepard is directed to two-piece "implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." *Shepard,* Abstract. The cancellous bone is described as having "lower mechanical strength . . . [which] prohibits its use in many surgical applications." In this two-piece implant, it is the cortical bone, not cancellous bone, that is load bearing, because Shepard teaches that the cancellous bone component is "the more brittle . . . portion of the graft." para. [0063]. While the outer peripheral surface of Shepard includes cortical, weight bearing bone on, at most, two sides, the other sides are made of non-weight bearing, lower mechanical strength, cancellous bone.

Because Shepard does not teach either expressly or inherently the presently claimed outer peripheral surface of load bearing material, Shepard cannot anticipate the current claims. The Examiner's rejection should be withdrawn.

C. The bores of Shepard are not within the scope of the "bores" as presently claimed.

Shepard simply does not teach either an "instrument-receiving bore formed in the outer peripheral surface," or a bore "having a diameter and a length [that] . . . substantially match a diameter and length of an implant engaging portion of an implant insertion instrument . . . [in order to displace] force from the implant insertion instrument . . . over a relatively wide area of the bore" as recited in present claims 21 and 36. In addition, the implant of Shepard is not intended to be manipulated by an implant insertion instrument through engagement of the bores.

1. The bores of Shepard are not "instrument receiving bore[s]" as presently claimed.

The Examiner cites Shepard for teaching an "instrument receiving bore," but the bores of Shepard are not intended to receive an instrument. On the contrary, the bores of Shepard are designed to receive pins which allow the two pieces of the implant to be secured. Shepard is explicit: the "plurality of bores are cut through the cortical bone member and into the [cancellous] member to hold pins which are angularly inserted into the bores." *Shepard,* para. [0021]. The pins of Shepard, inserted into the bores, would prevent insertion of an implant engaging portion of an implant insertion instrument into the bores as presently claimed, and without the pins the implant is unstable.

The Examiner argues that the pin receiving bores of Shepard are the same as the presently claimed bores because "the bores [could be engaged by the instrument] prior to the insertion of the pins." *Office Action,* p. 7. But as stated above, the cancellous component is brittle and the pins are designed to stabilize the two components so that the implant may be inserted into a prepared surgical site. Thus, without the pins inserted into the bores, the implant is unstable and could not be moved into place by manipulating it with an instrument. Further, Shepard teaches that the brittle cancellous portion of the implant cannot withstand tapping from an instrument. See para. [0063] ("the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancerous [sic] portion of the graft.").

A device that cannot withstand tapping is unlikely to withstand the torque applied by the instrument in positioning the implant within the inter-vertebral space.

Because Shepard does not expressly or inherently describe an "instrument receiving bore" for receiving "an implant engaging portion of an implant insertion instrument," Shepard cannot anticipate the current independent claim. The Examiner's rejection should be withdrawn.

2. *Shepard does not teach a "bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant insertion instrument is displaced over a relatively wide area of the bore."*

The Examiner asserts that Shepard discloses: "an instrument receiving bore (44 or 46) formed in the outer peripheral surface at the anterior end . . . having a diameter and a length wherein the diameter and length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument." *Office Action*, p. 3. But the Examiner mischaracterizes the disclosure of the Shepard reference.

Shepard does not teach that the disclosed bores may receive an implant engaging portion of an implant insertion instrument. On the contrary, the bores of Shepard are designed to receive "friction fit" pins of "biocompatible material having the necessary strength" to aid in stabilizing the two component implant. Para. [0063]. This is not a implant insertion instrument.

Further, without matching "bore . . . diameter and a length . . . [to] a diameter and length of an implant engaging portion" the force applied to the implant by the instrument would not be "displaced over a relatively wide area of the bore," as presently recited. This poor fit between bore and instrument would negatively affect the implant, because impact forces on the handle of the insertion instrument torque the instrument and the implant in the desired direction with minimum stress concentration on the implant in the bore to minimize damage to the bone that might otherwise occur in the presence of such stress concentrations. *Abstract,* paras. [0060] and [0061].

3. *The implant of Shepard is designed to be positioned by tapping with an instrument on the cortical bone surface rather than by the pin-receiving bores being engaged by an "implant engaging portion of an implant insertion instrument."*

Shepard specifically discusses ways to reorient the implant so as not to compromise the integrity of the implant:

> The cortical front is mated to the cancerous [sic] component with the crosspiece inner planar surface being adjacent the cancerous [sic] component. The cortical or load bearing component bears not only a compressive load but also serves as an impaction surface. Thus, the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancerous [sic] portion of the graft.

Shepard, para. [0063]. As is observed from the foregoing, Shepard teaches that a surgeon may orient the bone grafts by tapping the grafts with a suitable instrument, thus eliminating any need for a instrument receiving bore. Such tapping for placement is typical in the art, as discussed at paras. [0026]-[0027] of the present application.

Given that Shepard simply does not teach the bores receiving anything but pins, there is no basis for concluding that inserting an instrument into such bores would rise beyond the level of inserting a randomly selected instrument into a bore not suited for receiving such instrument.

For at least these reasons, Shepard does not anticipate the present claims. The Examiner's rejection is inapposite and should be withdrawn.

III. Claim Rejections Under 35 U.S.C. §103

According to the M.P.E.P., a proper obviousness rejection, based on combining aspects from various references, requires finding that the cited references included each claimed aspect "with the only difference between the claimed invention" and the cited references "being the lack of actual combination." M.P.E.P. § 2143(A), *See also In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974); *CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Additionally, if an independent claim is nonobvious under 35 U.S.C. § 103, "then any claim depending therefrom is nonobvious." § 2143.03, citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988).

In rejecting dependent claims 23, 25, 30, 31, and 35 as obvious, the Examiner relies on Shepard for teaching the aspects of claim 21 from which these claims depend. As described above, Shepard does not teach each and every aspect of independent claim 21, therefore claims 23, 25, 30, 31, and 35, which depend from claim 21 are also non-obvious.

Further, the Examiner's rejection also fails for the reasons presented below.

A. Claim 23 is not obvious under 35 U.S.C. § 103(a) over Shepard in view of McKay (US 6,261,586)

1. One of skill in the art would not look to McKay to modify the implant of Shepard.

According to the M.P.E.P., a proper obviousness rejection cannot be based on a modification of a reference that renders the reference unsatisfactory or inoperable for its original intended purpose. *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir. 1984); MPEP § 2143.01(V). Here,

modification of Shepard in view of McKay would render Shepard unsatisfactory for its intended purpose.

Shepard is directed to "implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." Shepard states that the intended use is "to provide a spinal fusion implant which uses a load bearing component member to take up the high forces which can arise between two vertebral bodies and a relatively porous cancellous component member to accelerate the healing process." Para. [0025]. As noted above, Shepard describes the non-load bearing cancellous component as brittle, and teaches that it should be shielded, even from tapping, when the implant is being positioned. Further, the two components of the Shepard implant must be stabilized by the presence of a "dove tail shape[]," and pins, which "provide additional stability." *Shepard*, Abstract.

McKay explicitly states the Examiner's proposed modification would create an unsatisfactory implant. For example, McKay describes bi-cortical implants, "porous cancellous bone between two cortical surfaces" (like the Shepard embodiments depicted in Figs. 24-28), as having "relatively poor biomechanical properties, in particular a low compressive strength," and therefore "not suitable as an intevertebral spacer without internal fixation due to the risk of collapsing." Background, Col. 2, l. 67 – Col. 3, l. 5. Thus, the device of Shepard is taught by McKay as having "poor biomechanical properties," even before it is modified with a central opening, which may increase the risk of collapse due to the lack of "internal fixation."

2. *There is no reasonable expectation of success in combining Shepard with McKay to create the presently claimed spinal bone implant body.*

"A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." M.P.E.P. § 2143.02, citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

In combining Shepard with McKay, the Examiner argues that "the central opening [of McKay] can be packed with an osteogenic composition to stimulate osteoinduction." *Office Action*, p. 5. The Examiner continues that "it would have been obvious to one of ordinary skill in the art at the time the invention was made . . . [that] the central opening can be packed with an osteogenic composition to stimulate osteoinduction." *Id.*

It is unreasonable to expect that one skilled in the art would could successfully modify the implant of Shepard, which requires pins for stability, with a central opening as in McKay without severely compromising Shepard's function.

McKay teaches a bone graft substitute including a composition of natural selectively deactivated bone material that has been processed to remove associated non-collagenous bone proteins. *McKay,* Abstract. McKay teaches a cortical bone graft having a chamber to receive osteoinductive material because the cortical bone graft generally is not osteoinductive:

> Preferably, the load bearing member is a bone graft obtained from the diaphysis of a long bone having a medullary canal which forms the chamber 25 ... The chamber 25 can be packed with an osteogenic composition to stimulate osteoinduction.

McKay, Col. 11, ll. 4-8. In contrast, Shepard solves the problem of McKay by disclosing a composite implant comprising a structural portion (the cortical component) and an osteoinductive portion (the cancellous component).

Further, as stated above, the Shepard two-component implant is unstable and the cancellous component is brittle. Pins are designed to stabilize the two components so that the implant may be inserted into a prepared surgical site, and the brittle cancellous portion of the implant cannot even withstand tapping from an instrument. Para. [0063] ("the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancerous [sic] portion of the graft."). Thus, one of skill in the art would not reasonably expect to modify the implant of Shepard with a destabilizing central opening in order to create the presently claimed spinal bone implant.

3. There is no motivation to combine Shepard with McKay.

A proper obviousness rejection based on some teaching, suggestion, or motivation to modify prior art requires at least a finding that there was some teaching, suggestion, or motivation to modify or combine prior art elements. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007); MPEP § 2143(G).

The Examiner attempts to use McKay as teaching a bone graft that may be used in the spine and having a central opening and a blind bore. The Examiner argues that "the central opening [of McKay] can be packed with an osteogenic composition to stimulate osteoinduction." The Examiner continues that "it would have been obvious to one of ordinary skill in the art at the time the invention was made . . . [that] the central opening can be packed with an osteogenic

composition to stimulate osteoinduction." But the Shepard implant already contains a centrally located osteoinductive material.

McKay teaches a bone graft substitute including a composition of natural selectively deactivated bone material that has been processed to remove associated non-collagenous bone proteins. *McKay,* Abstract. McKay teaches a cortical bone graft having a chamber to receive osteoinductive material because the cortical bone graft generally is not osteoinductive:

> Preferably, the load bearing member is a bone graft obtained from the diaphysis of a long bone having a medullary canal which forms the chamber 25 ... The chamber 25 can be packed with an osteogenic composition to stimulate osteoinduction.

McKay, Col. 11, ll. 4-8.

In contrast, Shepard purports to teach a composite implant comprising a structural portion (the cortical component) and an osteoinductive portion (the cancellous component). At the time of the invention of Shepard, Shepard was aware of implants formed of cortical long bones, such as McKay. Shepard identified shortcomings of such implants and developed the Shepard implant to overcome such problems:

> Cortical spacers are often shaped from cortical long bones, which are primarily found in the lower limbs and include, for example, femur, fibular, and the tibia bones. However, these long bones make up only a fraction of the available bone source. Cancellous bone, because of its superior osteoinductive properties, would be desirable to sue [sic] in the spinal implant. However, the lower mechanical strength of cancerous [sic] bones prohibits its use in many surgical applications.

Shepard, para. [0011]. Indeed, the specific need purportedly solved by Shepard is to combine the strength of cortical bone with the osteoinductivity of cancellous bone:

> Consequently, there is a need for an implant which should have with [sic] a load being compressive strength of 1000 to 5000 Newtons with a compressive load to be a minimum of 3000 Newtons as a safety factor. There is also a need to have a portion of cancerous [sic] bone immediately adjacent to the load bearing cortical zone to permit rapid ingrowth of a patient's own new bone with the cancellous bone forming the major part of the implant.

Shepard para. [0020]. Accordingly, Shepard already purports to solve the problem that the Examiner posits as the basis for modifying the implant of Shepard. Given that Shepard specifically claims that its non-cortical portion imparts osteoinductivity, there would be no motivation to further provide a central opening through Shepard to receive osteoinductive material.

4. Shepard teaches away from the presently claimed implant.

According to the M.P.E.P., a "reference must be considered in its entirety, i.e., as a whole, including portions that would lead away." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Here Shepard teaches away from the present implant.

As detailed above, Shepard identified shortcomings of the presently implant as being made from resources with limited availability, and therefore chose to develop an implant that would overcome such problems. *Shepard*, para. [0011]. Shepard teaches one of skill in the art that creating implants from long bones is undesirable because of limited availability of these products. In order to overcome the identified shortcomings, Shepard chose to combine the strength of cortical bone with the osteoinductivity of cancellous bone. *Shepard*, para. [0020].

Therefore, because Shepard teaches away from the presently claimed implant, the Examiner's rejection is inapposite and should be withdrawn.

B. Claim 25 is not obvious under 35 U.S.C. § 103(a) over Shepard in view of U.S. Pat. No. 5,766,252 to Henry et al. ("Henry").

The Examiner rejected claim 25 under 35 U.S.C. § 103(a) as unpatentable over Shepard in view of Henry. The Examiner argues that while "Shepard does not teach a central opening in communication with an anterior end bore . . .[, Henry discloses] a central opening in communication with an anterior end bore . . . , where the central opening can be promote fusion by being filled with bone graft material, and the bore can be used to engage an insertion tool." Applicant disagrees.

According to the M.P.E.P. a proper obviousness rejection cannot be based on a modification of a reference that renders the reference unsatisfactory or inoperable for its original intended purpose. *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir. 1984); MPEP § 2143.01(V). Here, modification of Shepard in view of Henry would render Shepard unsatisfactory for its intended purpose.

Shepard is directed to "implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." Shepard states that the intended use is "to provide a spinal fusion implant which uses a load bearing component member to take up the high forces which can arise between two vertebral bodies and a relatively porous cancellous component member to accelerate the healing process." Para. [0025]. As noted above, Shepard describes the non-load bearing cancellous component as brittle, and teaches that it should be shielded

from tapping when the implant is being positioned. Further, the two components of the Shepard implant must be stabilized by the presence of a "dove tail shape[]," and pins, which "provide additional stability." Abstract. Thus, combining Shepard with the central opening of Henry would render the Shepard device at least significantly less stable and unfit for its intended use.

Henry is directed to "[a]n interbody spinal prosthetic implant . . . placed between adjacent vertebral bodies of the vertebrae of a spine to maintain a desired orientation and spacing." Abstract. The Examiner argues that Henry could be combined with Shepard, because Henry teaches a "central opening can be promote fusion by being filled with bone graft material."

Henry further teaches that the body of the implant is "constructed of solid material for greater strength, enabling the rigid member . . . to withstand forces applied during insertion . . . [and] compressive forces encountered subsequently, during fusion[, wherein] . . . [t]he overall construction of the rigid member is a cage-like structure in which the solid tip . . . and the rear wall . . . are connected by longitudinal struts . . . for a rigid, sturdy yet open structure." *Id.* at 29-38 (emphasis added). There is no sturdy yet open structure in Shepard to surround the intended modification. On the contrary, the cancellous bone of Shepard is characterized as brittle, and it is the cortical bone that serves the function of load bearing and presumably structural stability.

Thus, the modification of Shepard in view of Henry would not result in a sturdy yet open structure, but rather would greatly destabilize the Shepard two-component device and render it unsuitable for its intended use.

C. Claim 30 is not obvious under 35 U.S.C. § 103(a) over Shepard in view of U.S. Pat. No. 5,554,191 to Lahille et al ("Lahille").

As discussed above, Shepard does not disclose the invention of claim 21. Lahille does not remedy the fundamental teaching deficiencies of Shepard. Lahille is directed to "[a]n intersomatic cage to be inserted from the posterior approach between two vertebrae comprises two substantially parallel branches for contact with the vertebral bodies . . . [wherein] the cage allows adjustment of the lordosis angle between the two vertebrae during surgery." Abstract. The Examiner cites Lahille as teaching a spinal implant which has roughened superior and inferior surfaces for the purpose of anchoring the prosthesis in place. Even if Lahille were to disclose such surfaces, the combination of Shepard and Lahille still would not teach the invention of the present claims.

Shepard and Lahille, in combination, do not teach an implant comprising a body having, among other things, a "bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore."

Because neither Shepard, nor Lahille teach the presently claimed aspects recited in independent claim 21, claim 30, which depends from claim 21, is also non-obvious. The Examiner's rejection is inapposite should be withdrawn.

D. Claims 31 and 35 were rejected under 35 U.S.C. § 103(a) as unpatentable over Shepard in view of U.S. Pat. Pub. No. 2002/0026242 to Boyle et al. ("Boyle").

As discussed above, Shepard does not disclose the invention of claim 21. Boyle does not remedy the fundamental teaching deficiencies of Shepard. Boyle teaches a ramp-shaped intervertebral implant including a body having an opening extending from upper and lower surfaces thereof. *Boyle*, para. [0038]. The Examiner cites Boyle as teaching an intervertebral implant which is made from a section of cortical bone from the diaphysis of a long bone. Even if Boyle were to disclose such surfaces, the combination of Shepard and Boyle still would not teach the invention of the present claims. Further, as discussed with respect to the rejection over Shepard in view of McKay, Shepard was aware of implants formed from a section of cortical bone. Shepard intended to address deficiencies of such implants. Accordingly, the Applicants submit that it would not be obvious to modify the implant of Shepard with the teachings of Boyle.

Shepard and Boyle, in combination, do not teach an implant comprising a body having, among other things, a "bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant adjustment instrument is displaced over a relatively wide area of the bore."

Reconsideration and allowance of claims 31 and 25 are thus respectfully requested.

E. Claim 37 is not obvious under 35 U.S.C. § 103(a) over Shepard.

The Examiner argues that although "Shepard does not teach the implant being made of a monolithic piece of cortical bone . . . [i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body of Shepard out of a monolithic

piece of cortical bone, since it has been held that constructing a formerly modular structure into one element involves only routine skill in the art."

Applicants disagree with the Examiner's rejection. Even if "it would not have been obvious to make the implant body of Shepard from a transverse section slice taken from the diaphysis of a long bone," Shepard does make claim 37 obvious for all the reasons stated above.

1. *Shepard does not teach "the substantial entirety of said superior and inferior surfaces for load bearing against respective adjacent vertebrae," of present claim 37.*

Shepard is directed to a "composite bone graft for use in implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." *Shepard,* Abstract. Thus, it is the "T-shaped cortical bone" that bears the load of the adjacent vertebrae, not the cancellous bone, which is described as having "lower mechanical strength . . . [which] prohibits its use in many surgical applications." Shepard makes explicit that it is the cortical bone, not cancellous bone that is load bearing, by describing the inventive implant as "a two piece, mated bone fusion block or spacer constructed with one component member of load bearing material preferably cortical bone and the other component member made of cancellous bone for use in orthopedic surgical procedures." *Shepard,* para. [0021] (emphasis added). This is simply not the presently claimed "substantial entirety of said superior and inferior surfaces for load bearing against respective adjacent vertebrae," because Shepard notes that cancellous bone is "the more brittle . . . portion of the graft," that must be protected from even tapping by a surgical instrument. *Id.,* [0063].

Shepard is directed to a two-piece "composite bone graft for use in implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." *Shepard,* Abstract. It is the "T-shaped cortical bone" that bears the load of the adjacent vertebrae, not the cancellous bone, which is described as having "lower mechanical strength . . . [which] prohibits its use in many surgical applications." In this two-piece implant, it is the cortical bone, not cancellous bone that is load bearing – "one component member of load bearing material preferably cortical bone and the other component member made of cancerous [sic] bone for use in orthopedic surgical procedures." *Shepard,* para. [0021] (emphasis added). Shepard also teaches that the cancellous bone is "the more brittle . . . portion of the graft." para. [0063]. While the outer peripheral surface of Shepard includes cortical, weight bearing bone on, at most, two sides, the other sides are of non-weight bearing, lower mechanical strength, cancellous bone.

2. *Shepard does not teach a "body having an outer peripheral surface substantially entirely of load bearing material," of present claims 21 and 36.*

Shepard is directed to a two-piece "composite bone graft for use in implants comprising a T-shaped cortical bone load bearing member mated to a [cancellous] member." *Shepard,* Abstract. It is the "T-shaped cortical bone" that bears the load of the adjacent vertebrae, not the cancellous bone, which is described as having "lower mechanical strength . . . [which] prohibits its use in many surgical applications." In this two-piece implant, it is the cortical bone, not cancellous bone that is load bearing – "one component member of load bearing material preferably cortical bone and the other component member made of [sic] ous bone for use in orthopedic surgical procedures." *Shepard,* para. [0021] (emphasis added). Shepard also teaches that the cancellous bone is "the more brittle . . . portion of the graft." para. [0063]. While the outer peripheral surface of Shepard includes cortical, weight bearing bone on, at most, two sides, the other sides are of non-weight bearing, lower mechanical strength, cancellous bone.

While Shepard teaches an alternative embodiment having two cortical components with the cancellous component positioned between (Figs. 24-29), as described above, the cancellous portion of the outer peripheral surface of Shepard is non-weight bearing.

Because Shepard does not teach either expressly or inherently the presently claimed outer peripheral surface substantially entirely of load bearing material, Shepard does not make the current claims obvious. The Examiner's rejection should be withdrawn.

3. *The bores of Shepard are not the bores as presently claimed.*

Shepard simply does not teach either an "instrument-receiving bore formed in the outer peripheral surface," or a bore "having a diameter and a length [that] . . . substantially match a diameter and length of an implant engaging portion of an implant insertion instrument . . . [in order to displace] force from the implant insertion instrument . . . over a relatively wide area of the bore" as recited in present claims 21 and 36. In addition, the implant of Shepard is not intended to be manipulated by an implant insertion instrument through engagement of the bores.

a. The bores of Shepard are not "instrument receiving bore[s]" as presently claimed.

The Examiner cites Shepard for teaching an "instrument receiving bore," but the bores of Shepard are not intended to receive an instrument. On the contrary, the bores of Shepard are designed to receive pins which allow the two pieces of the implant to be secured. Shepard is

explicit, the "plurality of bores are cut through the cortical bone member and into the [cancellous] member to hold pins which are angularly inserted into the bores." The pins of Shepard, inserted into the bores, would prevent insertion of an implant engaging portion of an implant insertion instrument into the bores as presently claimed.

The Examiner states that the pins could be inserted into the Shepard implant after removal of an implant insertion instrument. But as stated above, the cancellous component is brittle and the pins are designed to stabilize the two components so that the implant may be inserted into a prepared surgical site. Without the pins inserted into the bores, the implant would be unstable. Further, Shepard teaches that the brittle cancellous portion of the implant cannot withstand tapping from an instrument, and likely would also not withstand torque exerted on the implant. Thus placement of the pins after manipulation with an implant insertion instrument would render the implant unusable.

Because Shepard does not expressly or inherently describe an "instrument receiving bore" for receiving "an implant engaging portion of an implant insertion instrument," Shepard cannot make the current independent claim obvious. The Examiner's rejection should be withdrawn.

> *b. Shepard does not teach a "bore having a diameter and a length wherein the diameter and the length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument such that force from the implant insertion instrument is displaced over a relatively wide area of the bore."*

The Examiner asserts that Shepard discloses: "an instrument receiving bore (44 or 46) formed in the outer peripheral surface at the anterior end . . . having a diameter and a length wherein the diameter and length substantially match a diameter and length of an implant engaging portion of an implant insertion instrument." *Office Action*, p. 3. But the Examiner mischaracterizes the disclosure of the Shepard reference.

Shepard does not teach that the disclosed bores may receive an implant engaging portion of an implant insertion instrument. On the contrary, the bores of Shepard are designed to receive "friction fit" pins of "biocompatible material having the necessary strength." para. [0063]. This is not a implant insertion instrument.

Further, without matching "bore . . . diameter and a length . . . [to] a diameter and length of an implant engaging portion" the force applied to the implant by the instrument would not be "displaced over a relatively wide area of the bore." This would negatively affect the implant, because impact forces on the handle of the insertion instrument torque the instrument and

implant in the desired direction with minimum stress concentration on the implant in the bore to minimize damage to the bone that might otherwise occur in the presence of such stress concentrations. Abstract, paras. [0060] and [0061].

4. *The implant of Shepard is not designed to be engaged through the pin-receiving bores.*

Shepard specifically discusses ways to reorient the implant so as not to compromise the integrity of the implant:

> The cortical front is mated to the cancerous [sic] component with the crosspiece inner planar surface being adjacent the cancerous [sic] component. The cortical or load bearing component bears not only a compressive load but also serves as an impaction surface. Thus, the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancerous [sic] portion of the graft.

Shepard, para. [0063]. As is observed from the foregoing, Shepard teaches that a surgeon may orient the bone grafts by tapping the grafts with a suitable instrument, thus eliminating any need for a instrument receiving bore. Such tapping for placement is typical in the art, as discussed at paragraphs [0026]-[0027] of the present application.

Given that Shepard simply does not teach the bores receiving anything but pins, there is no basis for concluding that inserting an instrument into such bores would rise beyond the level of inserting a randomly selected instrument into a bore not suited for receiving such instrument.

CONCLUSION

This response is being submitted on or before July 6, 2010 (July 5th being a federal holiday), with the required fee for a 3-month extension of time, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

Date: 7/6/10

By: _____
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